MAY 1 4 2002



K020664

## 510(k) SUMMARY

**807.92(a) (1)**

| | |
|---|---|
| COMPANY NAME: | STERILOGIC WASTE SYSTEMS, INC. |
| COMPANY ADDRESS: | 6691 PICKARD DRIVE<br>SYRACUSE, NY 13211 |
| TELEPHONE:<br>FAX: | (215) 914-1110<br>(215) 914-0110 |
| CONTACT PERSON: | ERIK R. SYNNESTVEDT |
| SUMMARY PREPARATION DATE: | FEBRUARY 15, 2002 |

**807.92(a)(2)**

| | |
|---|---|
| TRADE OR PROPRIETARY NAME: | STERISHARP™ 3-GALLON RSDC |
| COMMON NAME: | REUSABLE SHARPS DISPOSAL CONTAINER |
| CLASSIFICATION: | CLASS II – ACCESSORY DEVICE |

**807.92(a)(3)**

**EQUIVALENT DEVICE #1: BEMIS SHARPS DISPOSAL CONTAINER (510[k] #K931664)**

CONTAINER LID: The Bemis Sharps Disposal Container lid ('lid") is used on the top of the SteriSharp™ 3 container. This Bemis Sharps Disposal Container has been approved under 510(k) #K931664.

**EQUIVALENT DEVICE #2: STERISHARP™ 2.5-GALLON RSDC (510[k] #K991662)**

CONTAINER BASE: The bottom portion of the unit (the "container") is a reusable polyethylene cavity with a wall thickness of 0.125" $\pm$ 0.002"similar to that of the SteriSharp™ 2.5. The SteriSharp™ 2.5 container has been approved under 510(k) #K991662.

**807.92(a)(4)**

DESCRIPTION:

The SteriSharp™ 3 is a reusable plastic sharps disposal container. It features a mail drop, torturous path tumbler lid for safe and easy disposal of sharps. Simply deposit syringes horizontally into the opening of the lid and they are deposited automatically into the container. When the container is full the tumbler will indicate that it is time to replace the unit. Just insert the locking tabs to secure the container in a closed position and replace it with a clean sanitized unit. Using our proprietary equipment, SteriLogic employees will empty and sanitize the unit and return it to your facility to use for the next switch out. The durable high-density polyethylene construction of the SteriSharp™ 3 makes it leak-proof, puncture resistant and stable. It meets or exceeds all OSHA recommendations for sharps containers, and because it is reusable, it is more environmentally friendly and less expensive than disposable alternatives.

**807.92(a)(5)**

INTENDED USE:

The SteriSharp™ 3 reusable container is intended for use by healthcare providers such as hospitals, laboratories, medical clinics, veterinary clinics, and other facilities where needles, sharps waste and other infectious waste is generated. The containers are designed to safely contain sharps waste prior to removal from generating facility and until ultimate treatment and disposal of waste. Containers are of such a design and material as to withstand emptying, unloading, washing and disinfecting for reuse according to 49 CFR Sections 178.603, 173.4465(d), 173.465(e) and 178.608.

**807.92(a)(6)**

The SteriSharp™ 3 reusable container is substantially equivalent to the Bemis Sharps Disposal Container in that the lid is identical; a semi-transparent natural colored polypropylene mail drop, torturous path tumbler lid. It is injection molded and varies in thickness from 0.05" to 0.07". The base container is similar in design and ergonomic characteristics to the Bemis Sharps Disposal Container. While the base of the Bemis unit is manufactured using polypropylene, the SteriSharp unit is manufactured with a thicker wall (0.125" $\pm$ 0.002" as compared to 0.06" $\pm$0.01") and stronger polymer (HDPE) to help confer reusable qualities.

| COMPARISON TABLE (LID) | Bemis 3-Gallon | SteriSharp™3 |
|---|---|---|
| Indications for use | healthcare sharps | same |
| Target population | healthcare professionals | same |
| Design | torturous path, mail-drop | same |
| Materials | polypropylene | same |
| Performance | single use | multiple use |
| Mechanical safety | mail-drop | same |
| Where used | healthcare facilities/labs | same |
| Standards met | 49 CFR / HD 22 (single use) | same/multi-use |

The SteriSharp™ 3 reusable container is also substantially equivalent to the SteriSharp™ 2.5 reusable container. They are both a combination of a polypropylene tumbler lid with a polyethylene base. The SteriSharp™ 2.5 base is a red, rotationally molded linear low density Polyethylene cavity while the SteriSharp™ 3 base is a red, injection molded high density polyethylene cavity. Both units are designed to be opened and sanitized automatically using the SteriLogic Sharps Consolidation Unit which is consistent with all applicable OSHA and DOH standards.

| COMPARISON TABLE (CONTAINER) | SteriSharp™2.5 | SteriSharp™3 |
|---|---|---|
| Indications for use | healthcare sharps | same |
| Target population | healthcare professionals | same |
| Design | rotationally molded | injection mold tapered |
| Materials | LLDPE | HDPE |
| Performance | multiple use | same |
| Where used | healthcare facilities/labs | same |
| Standards met | 49 CFR / HD 22 | same |

**807.92(b)(1)**

Over a two-day period from July 25, 2001 to July 26, 2001, all components of a random sampling of the SteriSharp™ 3 container were subjected to a simulated life-use of 100 cycles of closing, filling, depositing waste, opening, emptying, washing and sanitizing. A detailed report is included below under section "TAB 3." After simulated use, there were no visible signs of failure. Containers were then performance tested and passed. (see below)

**807.92(b)(2) and (3)**

The SteriSharp™ 3-Gallon RSDC meets and exceeds the primary design characteristics needed to comply with the OSHA Bloodborne Pathogens Standard. Data for the following tests have been provided and are as follows:

| | | | |
|---|---|---|---|
| Puncture | Health Devices 22 | Needle penetration force | Pass |
| Leak Resistance | Health Devices 22 | 24 hrs filled with water | Pass |
| Vibration | 49 CFR 178.608 | 1 hour repetitive bounce | Pass |
| Free Fall Drop | 49 CFR 178.603 | 5 drops 1.2 meter | Pass |
| Stacking | 49 CFR 178.606 | 24 hrs. under 30 kg | Pass |

"The package, as submitted and tested, visually appears to satisfy the test criteria and is capable of preventing the loss or dispersal of the contents for conditions normal to transport." (Container Testing Laboratory, Inc.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2002

Mr. Erik R. Synnestvedt
SteriLogic Waste Systems, Incorporated
6691 Pickard Drive
Syracuse, New York 13211

Re: K020664
Trade/Device Name: Sterisharp 3-Gallon RSDC, Model RSDC3G
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK and FMI
Dated: February 15, 2002
Received: March 1, 2002

Dear Mr. Synnestvedt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

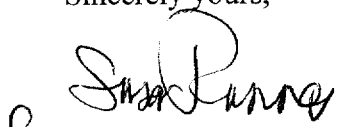
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) : K020664

DEVICE NAME : STERISHARP 3-GALLON RSDC, MODEL RSDC3G

INDICATIONS FOR USE :

The SteriSharp™ 3-Gallon RSDC reusable containers are intended for use by healthcare providers (hospitals, laboratories, medical clinics, veterinary clinics, and other such areas and facilities where needles, sharps waste and other infectious waste is generated). The containers are designed to safely contain sharps waste prior to removal from generating facility and until ultimate treatment and disposal of waste. Containers are of such a design and material as to withstand emptying, unloading, washing and disinfecting for reuse.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(per 21 CFR 801.109) (optional format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020664